(14) The statement: ''MEETS FDA POTENCY REQUIREMENTS.''

(15) If human blood was used in manufacturing the product, the statement: ''CAUTION: ALL BLOOD PRODUCTS SHOULD BE TREATED AS POTENTIALLY INFECTIOUS. SOURCE MATERIAL FROM WHICH THIS PRODUCT WAS DERIVED WAS FOUND NEGATIVE WHEN TESTED IN ACCORDANCE WITH CURRENT FDA REQUIRED TESTS. NO KNOWN TEST METHODS CAN OFFER ASSURANCE THAT PRODUCTS DERIVED FROM HUMAN BLOOD WILL NOT TRANSMIT INFECTIOUS AGENTS.''

(16) A statement of an observable indication of an alteration of the product, e.g., turbidity, color change, precipitate, that may indicate possible deterioration of the product.

(c) *Package insert.* Each final container of Blood Grouping Reagent shall be accompanied by a package insert meeting the requirements of § 809.10. If two or more final containers requiring identical package inserts are placed in a single package, only one package insert per package is required.

(d) *Names of antibodies.*

BLOOD GROUP DESIGNATION FOR CONTAINER LABEL

Anti-A	Anti-Jk^{b}
Anti-A$_1$	Anti-Js^{a}
Anti-A, B	Anti-Js^{b}
Anti-A and B	Anti-K
Anti-B	Anti-k
Anti-C	Anti-Kp^{a}
Anti-C^{w}	Anti-Kp^{b}
Anti-c	Anti-Le^{a}
Anti-CD	Anti-Le^{b}
Anti-CDE	Anti-Lu^{a}
Anti-Co^{b}	Anti-Lu^{b}
Anti-D	Anti-M
Anti-DE	Anti-M^{g}
Anti-Di^{a}	Anti-N
Anti-E	Anti-P$_1$
Anti-e	Anti-S
Anti-Fy^{a}	Anti-s
Anti-Fy^{b}	Anti-U
Anti-I	Anti-Wr^{a}
Anti-Jk^{a}	Anti-Xg^{a}

[53 FR 12764, Apr. 19, 1988, as amended at 59 FR 23637, May 6, 1994; 67 FR 9587, Mar. 4, 2002; 70 FR 14985, Mar. 24, 2005]

Subpart D—Reagent Red Blood Cells

SOURCE: 52 FR 37450, Oct. 7, 1987, unless otherwise noted.

§ 660.30 Reagent Red Blood Cells.

(a) *Proper name and definition.* The proper name of the product shall be Reagent Red Blood Cells, which shall consist of a preparation of human red blood cells used to detect or identify human blood-group antibodies.

(b) *Source.* Reagent Red Blood Cells shall be prepared from human peripheral blood meeting the criteria of §§ 660.31 and 660.32 of this chapter, or from umbilical cord cells which shall be collected and prepared according to the manufacturer's biologics license application.

[52 FR 37450, Oct. 7, 1987, as amended at 64 FR 56454, Oct. 20, 1999]

§ 660.31 Suitability of the donor.

Donors of peripheral blood for Reagent Red Blood Cells shall meet the criteria for donor suitability under § 640.3 of this chapter, except that paragraphs (b)(5) and (6), (d), and (e) of § 640.3 shall not apply.

§ 660.32 Collection of source material.

Blood for Reagent Red Blood Cells from donors of peripheral blood shall be collected as prescribed under § 640.4 of this chapter, except that paragraphs (c), (d), (g), and (h) of § 640.4 shall not apply.

§ 660.33 Testing of source material.

Except as provided in this section, a sample of each blood incorporated into the Reagent Red Blood Cell product shall be individually tested, with no fewer than two donor sources of each antibody specificity employed, to confirm the identification of all blood group antigens specified in the labeling as present or absent. The manufacturer shall perform at least one of the required tests for each factor. The Reagent Red Blood Cell product may be tested with a single donor source of antibody specificity if only one source of antibody is available, and the Director, Center for Biologics Evaluation and Research, has approved the use of